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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,172	03/19/2004	Leonard C. Jannusch	8195.35US01	7390

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EXAMINER	
MAHYERA, TRISTAN J	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,172	JANNUSCH ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 45-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicants' Remarks and Arguments filed on 8/8/2008 is acknowledged.

Status of the Claims

Claims 1-33 and 45-49 are pending and examined on the merits.

Specification

The objection to the specification has been **withdrawn** because the objected language was deleted from the specification in the Amendment filed 2/2/2008.

Claim Rejections - 35 USC § 103

Applicants' arguments have been considered and are found persuasive. Therefore the rejection of claims 1-33 and 45-49 under 35 U.S.C. § 103 is hereby **withdrawn**, however, in light of new art the claims are **newly rejected**.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 15-21 and 45-49 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over SCHIRALDI et al. (US RE. 33,093 see PTO-892) in view of VALAN (US 3,957,966 see PTO-892).

Claims 45-49 are product by process claims whereby the patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

SCHIRALDI teaches medicament-containing preparations for intra-oral use, specifically in the form of a very thin extruded thermoplastic film. See e.g. col. 1 lines 11-17; instant claims 1, 15, 19, 45 and 47. The film comprises 20-95% of hydroxypropyl cellulose (a thermoplastic polymer), 5-60% of a homopolymer of ethylene oxide and 2-10% of a plasticizer. See e.g. claim 1; instant claims 1, 21, 45, 47, 48. The film has a thickness of about 0.025-0.25 mm (see e.g. col. 2 lines 50-51) and can be a single or multi-layer film (see claim 1); instant claims 1 and 20. The film contains non-essential but customary ingredients, e.g. preservatives, antioxidants, flavors and colorants (see col. 4 lines 56-60; instant claim 7. The plasticizer used should be non-toxic and is present for the purpose of improving the polymer melt characteristics by reducing the polymer viscosity and thus reducing the force necessary when extruding the composition. See e.g. col 4 lines 45-49. The plasticizers taught include glycols, sorbitol and glycerol esters. See e.g. col 4 lines 38-42.

Claims 1, 16-18, 20-23, 25, 26 and 31-33 define specific ranges of wt%, perimeter area or thickness, all of which can be found through routine optimization depending on what one skilled in the art is attempting to accomplish, e.g. to alter the dosage the size/thickness/area of the film become result effective variables because an increase in size/thickness/area or wt% results in a dosage increase. See MPEP

2144.05 "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)."

SCHIRALDI does not teach the addition of the specific fatty alcohol plasticizers (although sorbitol as a plasticizer is taught), or the specific flavorants, sweeteners and bulking agents.

VALAN is used to teach the use of stearyl alcohol as a plasticizer in polymeric films.

VALAN teaches improved pharmaceutical preparations providing for the release of pharmacologically active materials over a controlled extended period of time using film coatings that protect products from light, oxygen, moisture or temperature. See e.g. Abstract and col. 1 lines 7-13. The coatings (i.e. films) comprise a polymer and a plasticizer, specifically stearyl alcohol. See e.g. claims 1 and 17:instant claims 1-6, 21 and 45 and 46. The plasticizers are used in an amount that depends upon what type of melt blend or emulsion is desired, for example, a melt containing 50% stearyl alcohol (as a plasticizer) will form soft and more flexible films and are thus suitable for the coating of food substances or tablets. See e.g. col. 4 line 65 to col. 5 line 2: instant claims 1, 21, 22 and 45

The references are silent with respect to the film dispersing in five minutes or less (30 seconds or less in claim 31) when in contact with a body fluid. The specification states "The term dispersible is used to mean that the film is configured to dissolve or break apart into small pieces." (see page 1 lines 11-12), however, the specification is silent regarding what percent of the film must dissolve before it is dispersed. Due to the lack of a precise definition, the term "dispersible" is given its broadest reasonable interpretation, which is any portion of the film that dissolves or

breaks apart is viewed as dispersed. Thus even in the instance when small portions (e.g. less than 1% of the film) dissolve, the film is considered to be dispersed. In light of this definition, it is the view of the Examiner that the film of the instant invention would be dispersed within the specified time because at least a portion of the film would dissolve.

Furthermore, applicants' composition, as claimed, is the same as the prior art. As, claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed dispersing properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have practiced a thermoplastic film comprising hydroxypropyl cellulose and about 50% fatty alcohol (stearyl alcohol) that has a perimeter of 15 cm sq and a thickness of less than 1 mm, which disperses in contact with body fluid in five minutes or less as taught by SCHIRALDI in view of VALAN. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition with stearyl alcohol because film coatings protect products from light, oxygen, moisture or temperature and 50% stearyl alcohol will form soft and more flexible films suitable for the coating of food substances or tablets, as taught by VALAN. Absent any evidence to the contrary, and based on the teachings of the prior art, there

would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 1, 7-14 and 22-33 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over SCHIRALDI in view of VALAN and in further view of MYERS et al. (US 2007/0122455 see PTO-892) as evidenced by ENGLESON (US 7,153,531 see PTO-892).

SCHIRALDI teaches medicament-containing preparations for intra-oral use, specifically in the form of a very thin extruded thermoplastic film, as described above.

VALAN is used to teach the use of stearyl alcohol as a plasticizer in polymeric coatings/films, as described above.

MYERS is used to teach bulking agents, flavorants and sweeteners for use in rapid-dissolving water-soluble film that incorporate an anti-tacking agent. The reference teaches that a variety of other components and fillers may be added to films, examples of these additives include bulking agents, sweetening agents and flavoring agents (see p[0120]. Bulking agents are known in the pharmaceutical or food composition arts to include dextrose and other carbohydrates. See e.g. ENGLESON claim 4; instant claims 10-13, 22, 25 and 33. Sweetening agents further include dextrose, artificial/synthetic sweeteners such as acesulfame-K and natural intensive sweeteners. See e.g. p[0099]; instant claims 14, 31 and 33. Flavoring agents include the mint oils (i.e. peppermint), menthol and citrus oils. See e.g. p[0093] and p[0096]; instant claims 7-9 and 24. The bulking agents, sweeteners and flavoring agents may be added in any desired amount,

up to about 80%, desirably about 3-50% and more desirably from about 3-20%. See e.g. p[0122].

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have practiced a thermoplastic film comprising HPC, fatty alcohols, dextrose, menthol or peppermint oil, and artificial sweeteners, as taught by SCHIRALDI in view of VALAN and in further view of MYERS. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition with dextrose because it acts as a filler or bulking agent useful in the pharmaceutical arts, with menthol or peppermint oil because of their breath freshening properties, and with artificial sweeteners because they result in enhanced sweetness and palatability making it ideal for oral films, as taught by MYERS. Absent any evidence to the contrary, and based on the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J. Mahyera/
Examiner Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615